**Statement of conformity with International Directives for Preventing Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy**

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| --- | --- |
| **Material Comercial Name** | Click here to enter text. |
| **Material Code (Used by Manufacturer)** | Click here to enter text. |
| **Manufacturer Name** | Click here to enter text. |
| **Production Site Address** | Click here to enter text. |

**This questionnaire must be answered by the qualified person of the manufacturers of raw materials and it has the objective of knowing the manufacturing processes of these materials in order to prevent the transmission of Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy.**

**Any changes in the manufacturing process of the material described above that can CHANGE THE STATUS OF THIS DOCUMENT must be immediately informed to Farmanguinhos.**

**Please, answer the following questions according to the manufacturing process of the material identified above:**

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| 1) Are the starting materials of the material partly or fully of animal or human origin (e.g. tissue, tissue extract or fluid such as milk, serum, blood)??[ ] **YES**[ ] **NO** |
| If **NO**, what are the origins of the starting materials? |
| [ ]  Vegetable[ ]  Synthetic[ ]  Fermentative / Cell Culture origin without any animal or human derived product in the broth[ ]  Inorganic[ ]  Other (specify below)**Click here to enter text.** |

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| 2) Are other materials (also reagents like chromatographic media, buffers etc.) of animal or human origin used in the manufacturing process of the material?[ ] **YES**[ ] **NO**☐ **Not applicable** |
| If **YES**, specify below:**Click here to enter text.** |
| 3) Are there procedures in place to avoid cross-contamination with residue of animal or human origin materials that come into contact with the equipment used to manufacture the material (e.g. other products and / or cleaning or disinfecting agents)?[ ] **YES**[ ] **NO**[ ] **Not applicable** (i.e., no animal/human origin materials come into contact with the equipment). |
| 4) If any material of animal or human origin is used in production (either as starting material or as other material, according to questions 1 and 2), please specify.[ ]  **Not applicable**[ ]  **Bovine (cattle)**[ ]  **Caprine (goat)**[ ]  **Ovine (sheep)**[ ]  **Human**[ ]  **Unknown**[ ]  **Other (specify below)****Click here to enter text.** |
| 5) If any material of animal or human origin is used in production (either as starting material or as other material, see questions 1 and 2 above), please specify the type of the material.[ ]  **Not applicable**[ ]  **Colagen**[ ]  **Milk or milk derivatives**[ ]  **Gelatin**[ ]  **Wool derivatives**[ ]  **Bovine blood or blood derivatives**[ ]  **Tallow derivatives**[ ]  **Peptones**[ ]  **Animal charcoal**[ ]  **Amino acids**[ ]  **Other (specify below)****Click here to enter text.** |
| 6) For tallow derivatives, animal charcoal, milk and milk derivatives, wool derivatives, amino acids and peptones:Does the material comply with the specific sourcing and manufacturing requirements described in Note for Guidance: Minimizing the risk of transmitting animal spongiform encephalopathy via human and veterinary medicinal products, EMA/410/01 current version?[ ] **YES**[ ] **NO**[ ] **Not applicable**If **NO**, is a TSE Certificate of Suitability (CEP\*) granted by EDQM?<http://www.edqm.eu/medias/fichiers/cep_procedure_revised_version.pdf>[ ] **YES**[ ] **NO**[ ] **Not applicable**If **NO**, please comment on the reason why no TSE CEP is available.**Click here to enter text.**\*CEP database <https://extranet.edqm.eu/publications/recherches_CEP.shtml> |

I do confirm that the material complies with the requirements of the Note for Guidance: Minimizing the risk of transmitting animal spongiform encephalopathy via human and veterinary medicines, EMA/410/01, current revision.

And I do certify that the information above is correct and can be verified.

**Issued by:**

|  |  |
| --- | --- |
| Name | **Click here to enter text.** |
| Job title | **Click here to enter text.** |
| Signature |  |
| Date |  |